

Patent 45198.00014.CON1

REMARKS

Claims 45-50 are pending. Claim 45 has been amended to include the term "type II." Claim 49 has been amended to read "disease or condition associated with increased insulin levels." Claim 50 has been amended to add the term "and a pharmaceutically acceptable carrier." Claims 46-47 were amended to eliminate the term "in need thereof" as unnecessary.

Claims 46 and 47 are allowed. Claims 45 and 48-50 stand rejected.

All of the above changes are cosmetic and none raise any issue of patentability. Both before and after the above changes, the invention was described in full, clear, concise, and exact terms and met all conditions for patentability under 35 USC 101 *et seq.* The scope of the claims of any resulting patent (and any and all limitations in any of said claims) shall not under any circumstances be limited to their literal terms, but are intended to embrace all equivalents. Accordingly, under no circumstances whatsoever may these claims be interpreted as:

- having been altered in any way for any reason related to patentability;
- having been narrowed;
- a concession that the invention as patented does not reach as far as the original, unamended claim;
- a surrender of any subject matter as a condition of receiving a patent; and/or, estopping applicants from asserting infringement against every equivalent, whether now known or later developed, foreseen or unforeseen;

Applicants also emphasize that the decision to address the Examiner's suggestions via claim amendment with the understandings set forth above is not in any way intended to avoid the "gatekeeping" role of the PTO with regard to the examination and issuance of valid patents for patentable inventions.

I. DOUBLE PATENTING REJECTIONS

The Examiner rejected claims 45, and 48-50 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 29, 36, and 38 of U.S. Patent No. 6,284,748. The Examiner notes that this patent is the grandparent of the current Application and then goes on to say:

Patent 45198.00014.CON1

A. Composition claim 50 is not patentably distinct from patent claim 1, which is drawn to the compounds. Compounds are embrative of the compositions, since a compound claim covers both the compound alone, or the compound mixed with another ingredient.

B. Claim 45 (and thus also claim 48) is drawn to "preventing diabetes". Diabetes can be prevented by suppressing any of the factors or processes which result in diabetes. Among the causes of diabetes (that is, among the things that diabetes is second to) are Genetic diseases most notably glycogen storage disease, (and other, such as Friedrich's ataxia and myotonic dystrophy). Thus, when Patent claim 36 is performed, which treats glycogen storage disease, it prevents the diabetes which results from glycogen storage disease. Thus, claim 45 is just somewhat broader than patent claim 36. Claim 48 is included because the claims language does not exclude a person who has glycogen storage disease. Indeed, certain forms of glycogen storage disease are directly associated with insulin resistance.

C. Claim 49 recites the treatment of atherosclerosis. Patent claim 38 is drawn to the treatment of this. More broadly, Patent claim 20 covers any disease derived from abnormally elevated insulin levels, which of course would include Diabetes mellitus Type II, which in turn covers all but the third choice in claim 49 (which is covered only to a limited extent). Thus, the treatment branch of claim 49 is just a narrower version of patent claim 20. (Office Action pp. 2-3)

The Applicants respectfully traverse this rejection.

A. The Applicants note that they have amended claim 50 to include the term "and a pharmaceutically acceptable carrier." Current claim 50 requires an additional limitation, "a pharmaceutically acceptable carrier." Therefore, claim 50 of the current application does not claim the same invention as claimed in claim 1 of the '748 patent.

B. As the Applicants are herewith filing a Terminal Disclaimer over U.S. Patent No. 6,284,748, they believe that this rejection is moot.

C. As the Applicants are herewith filing a Terminal Disclaimer over U.S. Patent No. 6,284,748, they believe that this rejection is moot.

Patent 45198.00014.CON1

II. 35 USC § 112 REJECTIONS**A. Second Paragraph, Indefiniteness**

1. The Examiner has rejected claim 45 under 35 USC § 112, second paragraph as indefinite.

The Examiner says:

The term "Diabetes" is ambiguous in claim 45. It is not a complete term. Diabetes insipidus for example is caused by the inability of the kidneys to conserve water, which is caused by a lack of ADH (central diabetes insipidus) or by failure of the kidneys to respond to ADH (nephrogenic diabetes insipidus). Diabetes mellitus is a collection of metabolic disorders. (Office Action p. 4)

The Applicants respectfully traverse this rejection.

The specification at page 1, lines 9-10 clearly indicates that the term "diabetes" refers to diabetes mellitus. According to MPEP 2173.02, the claim language:

must be analyzed , not in a vacuum, but in light of:

(A) The content of the particular application disclosure:

(B) The teachings of the prior art: and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Therefore a person of ordinary skill in the art upon reading the specification would clearly understand that the term "diabetes" refers to diabetes mellitus. Consequently, the term is not indefinite.

In view of the above, the Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

2. The Examiner has rejected claim 50 under 35 USC § 112, second paragraph as indefinite.

The Examiner says:

Patent 45198.00014.CON1

A complete and proper composition claim must recite a carrier, otherwise it is just a compound claim. A carrier is thus needed for the claim. (Office Action p. 4)

The Applicants have amended claim 50 to add the phrase "pharmaceutically acceptable carrier."

In view of the above, the Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

B. First Paragraph, Enablement

1. The Examiner has rejected claim 45 under 35 USC § 112, second paragraph as not enabled.

The Examiner states:

Diabetes in general cannot be prevented. What is preventable are forms of diabetes which are secondary to some other problem. For example, diabetes can be secondary to some pancreatic disease such as chronic pancreatitis, to cirrhosis, to some endocrine disease such as Cushing's syndrome, some genetic diseases such as glycogen storage diseases, Friedreich's ataxia, myotonic dystrophy, and assorted conditions such as hyperinsulinemia which lead to diabetes. But other forms, such as Type I, are not preventable. There is no evidence of record that such compounds, or indeed any known compounds with this mode of action, can prevent diabetes in general, even if limited to diabetes mellitus. (Office Action p. 4)

The Applicants respectfully traverse this rejection.

However, in order to advance the prosecution of this Application, the Applicants have amended claim 45 to read "type II diabetes."

In view of the above, the Applicants respectfully request that the Examiner withdraw the enablement rejection.

2. The Examiner has rejected claim 49 under 35 USC § 112, second paragraph as not enabled.

The Examiner states:

Patent 45198.00014.CON1

The claim, insofar as it covers either the treatment or prevention of "ischemic injury" cannot possibly be enabled for such a scope. Ischemia is an insufficient supply of blood to any organ in the body, and thus, this covers any injury that arises from this. The injury could arise from the failure of blood to provide e.g. nutrients or oxygen, or the failure of the blood to remove waste products such as metabolites. It can arise from a blocked artery (which can come from many sources such as blood clots or artery contractions. Large numbers of causes have been assigned to such blockages, such as Smoking, High blood pressure, obesity, stress and anger, most of which have nothing at all to do with insulin. The other three items as[sic] specific disorders, but are similarly problematic. These can also arise from sources having nothing whatsoever to do with insulin. (Office Action p. 5)

The Applicants respectfully traverse this rejection.

However, in order to advance the prosecution of this Application, the Applicants have further clarified claim 49 by amending it to read "a disease or condition associated with increased insulin levels."

In view of the above, the Applicants respectfully request that the Examiner withdraw the enablement rejection.

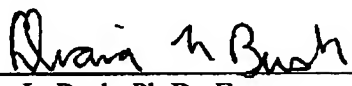
Patent 45198.00014.CON1

CONCLUSION

In view of the foregoing remarks, it is believed that the application is in condition for allowance, and such action is respectfully requested at the Examiner's earliest convenience.

Respectfully submitted,

Dated: 11/17, 2004


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